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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,477	07/30/2001	Adrian Bot	17945.014	3914

7590

04/18/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/18/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

919477

Applicant(s)

BOT et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-80 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-80 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31 and 61-80, drawn to microparticle compositions comprising a surfactant, excipient and antigen, classified in class 424, subclass 184.1+ and 278.1+.
- II. Claims 32-41 and 51-55, drawn to microparticle compositions, classified in class 424, subclass 184.1+ and class 514, subclass 23+.
- III. Claims 42-50 and 56-60, drawn to methods of treating patients with autoimmune disorders, classified in class 424, subclass 184.1+ and class 514, subclass 23+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different ingredients and operate differently, because there is no limitation in Group I that anything provided in the excipient bind to a lectin receptor on antigen presenting cells.

Inventions I/II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product has different uses. The microparticles could be used to enhance desired immune responses, as well as to suppress/tolerize autoimmune responses.

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Also, microparticles can be used in various formats of immunoassays as labels, solid phases, or sequestering means.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.

In the event that Group I is elected the following election of species is stated:

Group I
Claims 1-31 and 61-80 are generic to a plurality of disclosed patentably distinct species comprising the various Markush group members of excipients recited in claim 70 (which recites these more specifically than either claim 1 or 61). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The Markush group members of excipients recited in claim 70 has diverse members with no recognized common function (e.g. carbohydrates, salts, amino acids, peptides/proteins, saponins, synthetic polymers); thus, a reference showing one would not suggest the other for a function such as suppressing or tolerizing an immune response.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Groups I-III
In the event applicant elects any of Groups I-III, the following election of species is

stated:

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Claims 1-80 are generic to a plurality of disclosed patentably distinct species comprising various specific surfactants as recited in the Markush groups of claims 15-23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. The Markush group of surfactants recited in claims 15-23 has diverse members with no recognized common function (e.g. phosphatides of various specific types, amino acids/proteins of various types, numerous types of synthetic detergents/polymers); thus, a reference showing one would not suggest the other for a function such as suppressing or tolerizing and immune response.

In other words, if Group I is elected applicant must elect a combination of a specific surfactant and a specific excipient. Applicant must clearly state which elected member is the surfactant and which is the excipient, since there are members common to both (e.g. amino acids and proteins).

If Group II or III is elected applicant must elect a specific surfactant.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon-Thu from 8:00 to 5:30. The examiner can also be reached on alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644